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September 30, 2021
The Honorable Christopher J. Burke
United States District Court for the District of Delaware
844 N. King Street
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PUBLIC VERSION OF D.I. 154
FILED: OCTOBER 7, 2021

Re: *Speyside Medical, LLC v. Medtronic CoreValve, LLC et al,*
Case No. 1:20-cv-00361-LPS-CJB

Dear Judge Burke:

Defendants Medtronic CoreValve, LLC and Medtronic, Inc. (“Medtronic”) move for leave to amend its Answer to the Second Amended Complaint (D.I. 81) to add an affirmative defense that two of Speyside’s five asserted patents are unenforceable under the doctrine of prosecution laches.¹ The Federal Circuit recently clarified the defense of prosecution laches such that the defense may now be a viable defense against patents filed after 1995. Medtronic has good cause to amend. Because Medtronic moved diligently to meet and confer with Speyside, serve an amended interrogatory response, and file this motion, Speyside will not be prejudiced. Thus, Medtronic respectfully requests the Court follow the Third Circuit’s policy of deciding defenses on their merits and allow Medtronic to amend its answer to add a defense of prosecution laches.

I. Nature and Stage of Proceedings. Speyside filed this action on March 13, 2020 asserting five patents, including U.S. Patent Nos. 9,510,941 (the “941 patent”); and 10,449,040 (the “040 patent”). On October 15, 2020, the Court entered the proposed scheduling order which set the deadline to file motions to amend pleadings on March 5, 2021 and the deadline to complete fact discovery on November 23, 2021. D.I. 35. Significant discovery remains in that time. No depositions have been taken, and the parties continue to meet and confer regarding the completeness of each side’s produced discovery. Dispositive motions are due April 13, 2022, and trial is set to begin October 11, 2022. *Id.* On August 31, 2021, Medtronic renewed its motion to stay the case pending the final written decisions on Medtronic’s instituted IPRs.² D.I. 134.

II. Legal Standard. When a party seeks leave to amend, “[t]he court should freely give leave when justice so requires” to amend pleadings. Fed. R. Civ. P. 15(a)(2). The Third Circuit has adopted a liberal approach to the amendment of pleadings to ensure that “a particular claim will be decided on the merits rather than on the technicalities.” *Dole v. Arco Chemical Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990). Leave to amend accordingly should be granted unless Speyside demonstrates undue delay, prejudice, bad faith, dilatory motive, or futility. *See Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006).

¹ Attached hereto are the Amended Answer to Speyside’s Second Amended Complaint (Ex. A) and a blackline to the Amended Answer to Speyside’s Second Amended Complaint (Ex. B). Pursuant to Local Rule 7.1.1, the parties conferred, and Speyside opposes.

² As noted in its renewed motion to stay, Medtronic believes that should the motion to stay be granted, the decision on this motion to amend may also be stayed. D.I. 135, at 4 n.2.

When the deadline to amend has passed, the requesting party must show “good cause” to amend. Fed. R. Civ. P. 16(b)(2). Good cause exists if, despite diligence, Medtronic could not have reasonably sought the proposed claim in a timely manner. *Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 371 (D. Del. 2009). In conducting a good cause analysis, Courts weigh the likelihood of prejudice to the nonmovant. *Id.* at 374.

III. Good Cause Exists Because of the Recent Federal Circuit *Hyatt* Decision. On June 1, 2021, the Federal Circuit’s *Hyatt* decision clarified that the defense of prosecution laches may extend to patents filed after June 8, 1995, when the terms of U.S. patents changed from 17 years after issuance to 20 years from filing. *See Hyatt v. Hirshfeld*, 998 F.3d 1347 (Fed. Cir. 2021). An equitable defense, prosecution laches “render[s] a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under a totality of the circumstances.” *Id.* at 1359-60. Prior to *Hyatt*, prosecution laches jurisprudence was sparse and focused on pre-1995 so-called “submarine” patents, whose issuance and publication are intentionally delayed by the applicant for a long time. *Id.* at 1352.

Following *Hyatt*, on August 5, 2021, Chief Judge Gilstrap in the Eastern District of Texas found a patent unenforceable under the doctrine of prosecution laches. *Personalized Media Commc’ns, LLC v. Apple Inc.*, 2021 WL 3471180 (E.D. Tex. Aug. 5, 2021). The Court noted “[w]hether an applicant’s delay is unreasonable is a fact-intensive inquiry that depends on the specific circumstances.” *Id.*, at *16. The Court conducted a lengthy analysis of the totality of those circumstances, numbering thirty-seven paragraphs of conclusions of law. *Id.* at *16-*21. The Court looked to factors like the length of delays in prosecution, the complexity of the applications, and prejudice to the accused when the prosecution delays mean the applicant is submitting claims and amendments based on the accused’s product available on the market. *Id.*

Commentators have viewed these cases as an evolution of the law of prosecution laches such that the defense may now be applicable to post-1995 patents. Ex. C (Law 360, “Nuked Apple Verdict Highlights Potential New Patent Defense”); Ex. D (JD Supra, “After *Hyatt v. Hirshfeld*, It Might Be Time to Pay Attention to Prosecution Laches”). For instance, in an August 11, 2021 article, one commentator noted the *Hyatt* and *PMC* decisions highlight a “potential new patent defense” because this “rarely invoked rule” may be applicable when “the inventor delays the application process, potentially casting a shadow on some common filing strategies.” Ex. C.

Good cause exists for Medtronic to amend because only recently did the Federal Circuit and other courts provide guidance that this defense may apply to post-1995 patents, like those asserted by Speyside. *See Clark v. Target Corp.*, 2020 WL 772871, at * 1 (D.S.C. Feb. 18, 2020) (finding good cause to extend deadline to amend pleadings due to recent change in law); *Shank v. Carleton Coll.*, 329 F.R.D. 610, 615 (D. Minn. 2019) (noting a change in law may constitute good cause); *Pumpco, Inc. v. Schenker Intern., Inc.*, 204 F.R.D. 667, 668 (D. Colo. 2001) (finding good cause to extend scheduling order deadline when amendment was based, in part, on a recent change in the law). Since the decisions issued in June and August, after the deadline to amend, Medtronic cannot reasonably have been expected to raise the defenses prior to the deadline.

Once Medtronic became aware of the availability and viability of its proposed prosecution laches defense, it acted diligently in investigating the defense, conferring with Speyside, bringing the instant motion, and seeking leave to amend to add the defense without undue delay. Because

Medtronic only recently developed the Rule 11 basis for asserting this defense, and because Speyside will experience no prejudice (as noted below), Medtronic has good cause to amend.

IV. Speyside will not be prejudiced. The burden is on the nonmoving party to prove it will be prejudiced because an amendment “causes surprise, results in additional discovery, or adds costs to the litigation in defending against the new facts or theories alleged.” *Aerocrine AB v. Apieron Inc.*, 2010 WL 1225090, at *7 (D. Del. Mar. 30, 2010). To prove prejudice, the non-moving party “must do more than merely claim prejudice; it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the amendments been timely.” *Cordance Corp.*, 255 F.R.D. at 371.

Speyside is not prejudiced by Medtronic’s proposed amendment to assert a defense of prosecution laches as to the ’040 and ’941 patents. Speyside will not need to expend any additional resources to conduct discovery or prepare for trial. Speyside has unique knowledge of information related to Medtronic’s proposed prosecution laches defense as assignee and holder of the rights and interest in those patents. Significant additional discovery should not be necessary because information relevant to the prosecution laches defense, including the prosecution history of the ’040 and ’941 patents, has already been exchanged during discovery. Indeed, Medtronic served a supplemental response to Speyside’s interrogatory identifying the facts and law supporting Medtronic’s defense. Ex. E.

Moreover, Speyside will not be deprived of any opportunity to rebut the prosecution laches defense. The parties have nearly three months remaining in fact discovery, which is ample time for Speyside to take any additional discovery it requires with regard to this defense. No depositions have been taken, and fact discovery does not close until November 23, 2021. The deadline for opening expert reports is not until January 14, 2022, and trial is not scheduled to begin until October 11, 2022. Therefore, Speyside would not be prejudiced by the amendment.

V. There has been no undue delay, bad faith, or dilatory motive. Medtronic has not acted with undue delay, bad faith, or dilatory motive in seeking to amend its Answer. While the deadline to amend pleadings passed in March, Medtronic could not have reasonably raised the defense prior to the issuance of the *Hyatt* and *Personalized Media* decisions. When those decisions issued, Medtronic promptly investigated, met and conferred with Speyside, supplemented its interrogatory responses, and filed this motion. Medtronic’s actions demonstrate Medtronic has acted diligently, not with any dilatory motive.

VI. Medtronic’s amendment is not futile. An amendment is futile if “the [pleading], as amended, would fail to state a claim upon which relief could be granted.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). Medtronic’s proposed amendment adequately pleads the defense of prosecution laches sufficient to “raise a right to relief above the speculative level, on the assumption that all the allegations in the [proposed amendment] are true.” *Cordance Corp.*, 255 F.R.D. at 374 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)); see Ex. A at 14. Medtronic has adequately pleaded the defense in its Proposed Amended Answer (Ex. A) and has provided further information to Speyside in Medtronic’s supplemental interrogatory response (Ex. E).

VII. Conclusion. For the foregoing reasons, the Court should grant Medtronic’s motion to amend and allow its prosecution laches defense to be heard on its merits.

Respectfully submitted,

DLA Piper LLP (US)

/s/ Brian A. Biggs

Brian A. Biggs (DE Bar No. 5591)

Counsel for Defendants.

cc: All Counsel of Record